JUL 29 2011 K111906

510(k) Summary for the XCELA™ HYBRID PICC WITH PASV™ VALVE TECHNOLOGY

Date prepared: 11-May-2011

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

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and

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508-658-7929

C. Device Name

Trade Name:	XCELA™ HYBRID PICC WITH PASV™ VALVE TECHNOLOGY
Common/Usual name:	
Classification Name:	Peripherally Inserted Central Catheter (PICC) Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Premarket Notification(s):	K101326, K091261, K093366

E. Device Description

The Xcela™ Hybrid PICC with PASV™ Valve Technology are flexible radiopaque catheters with suture wings for catheter securement, extension tubes(s) which connect to proximally located luer lock adapter(s) with two pressure activated safety valves (PASV™), available in a triple lumen configuration; a reverse tapered shaft to aid in staunching bleeding at the insertion site and a non-valved lumen for central venous pressure monitoring.

The lumens are differentiated by proximally located colored extension tube clamps and/or colored luer adaptors, with gauge descriptor, if the lumen is rated for power injection the maximum power injection flow rates, and "NO CT" for non-power injectable lumens.

The Xcela™ Hybrid PICC with PASV™ Valve Technology is designed with the option of being used with power injectors for the administration of contrast media for imaging studies such as Computerized Tomography (CT) scans and Magnetic Resonance Imaging (MRIs).

The catheters are available as single, sterile packages with a variety of procedural accessories in standard kit configurations and as a convenience to suite specific clinical needs.

F. Intended Use

The Xcela™ Hybrid PICC with PASV™ Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela™ Hybrid PICC with PASV™ Valve Technology is 6 mL/sec.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed device has similar materials, design, components and technological characteristics as the predicate intravascular catheters.

The predicate devices are offered in sizes 3 F to 6 F outside diameter, single and multi-lumen (dual and triple) models, whereas the proposed device is offered in 6 F outside diameter, multi-lumen (triple); both predicate and proposed devices offer PASV valved and non-valved models, and are for optional use to power inject contrast media.

H. Substantial Equivalence

Based on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.

I. Performance Data

The performance evaluation of the Xcela™ Hybrid PICC with PASV™ included testing conducting in accordance with the following FDA guidance document and international standards with successful results:

- EN ISO 10555-1:2009, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 COR 2002, *Sterile, Single-Use Intravascular Catheters – Part 3: Central Venous Catheters*
- FDA's "*Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters dated March 16, 1995*"

The testing performed is summarized below:

Performance Testing – Proposed 6F Triple Lumen Hybrid PICC with PASV™

Test	Test Objective	Test Result
1.	Product Labeling: Verify catheter is labeled correctly.	PASS
2.	Central Venous Pressure Monitoring: Verify that catheter can monitor central venous pressure (Non-Valved Lumen Only)	PASS
3.	Luer Connection: Verify luer to EN 1707	PASS
4.	Assembly Leak Strength: Verify the catheter assembly does not leak simulating the method in ISO 10555-1 clause 4.6.1.	PASS
5.	Assembly Aspiration Strength (Closed Ended): Verify catheter assembly does not leak simulating the method in ISO 10555-1 clause 4.6.2.	PASS
6.	Assembly Aspiration Strength (Open Ended): Verify the catheter assembly does not leak simulating the method in ISO 10555-1 clause 4.6.2.	PASS
7.	Priming Volume: Verify the priming volume of the catheter	PASS
8.	Power Injection Flow Rate: Verify the catheter can meet its labeled flow rate.	PASS
9.	Power Injection Multiple Injections: Verify catheter can withstand multiple simulated use injections at the maximum target flow rate.	PASS
10.	Static Burst: Verify catheter does not leak/burst when taken to failure below the minimum requirement.	PASS
11.	Oversleeve to PASV™ Valve Housing and Hybrid Luer Tensile Strength: Verify force at break of the valve housing to oversleeve and hybrid luer to oversleeve simulating the method in ISO 10555-1 clause 4.5 and ISO 10555-3 clause 4.7.	PASS
12.	Gravity Flow Rate: Verify gravity flow rate of the catheter simulating the method in ISO 10555-3 clause 4.6.	PASS
13.	Long term Extension Tube Life (Non-valved lumen): Verify effectiveness of extension tube to undergo repeat clamping without cracking or leaking	PASS
14.	Long Term Clamp Life (Non-Valved lumen): Verify effectiveness of clamp to undergo repeat clamping without cracking.	PASS
15.	Long Term Clamp Life Compatibility with Extension Tube (non-Valved lumen): Verify effectiveness of clamp and extension tube to not leak after repeat clamping.	PASS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lorraine M. Hanley
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Navilyst Medical, Incorporated
26 Forest Street
Marlborough, Massachusetts 01752

JUL 29 2011

Re: K111906
Trade/Device Name: Xcela™ Hybrid PICC with PASV™ Valve Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous Implanted Long-term Intravascular Catherter
Regulatory Class: II
Product Code: LJS
Dated: June 30, 2011
Received: July 5, 2011

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/ CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): _____

Device Name: Xcela™ Hybrid PICC with PASV™ Valve Technology

Indications for Use:

The Xcela™ Hybrid PICC with PASV™ Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela™ Hybrid PICC with PASV™ Valve Technology is 6 mL/sec.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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